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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,561	02/19/1999	YOSHIHIRO SATO	10235/4	1215

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/05/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,561

Applicant(s)

SATO, YOSHIHIRO

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,25,29,32-34 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,25,29,32-34 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 24
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

1. This action is in response to papers filed 19 February 2002 in Paper No. 23 in which claims 34, 37 and 38 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 22 dated 19 November are withdrawn in view of the amendments and Applicant's Arguments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Currently claims 21, 22, 25, 29, 32-34 and 37-39 are under prosecution.

Claim Rejections - 35 USC § 112

First paragraph of 35 U.S.C. 112: Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21, 22, 25, 29, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a process for reducing evaporation in a minute droplet of an aqueous solution, but the specification does not provide an adequate written description of the claimed invention. The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the

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application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol. 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Reduction to practice

The claims are drawn to a process for reducing evaporation in a minute droplet of an aqueous solution. The claimed process encompasses a very large genus of aqueous solutions, biological and non-biological, each comprising a myriad of components each comprising a very large genus of component concentrations and each comprising a very large genus solution of characteristics e.g. pH, thermal properties, and viscosities. Each of the very large genus of claimed species requires specific preparations and conditions to obtain the claimed results i.e. reducing evaporation. However, the specification does not describe an actual reduction to practice of the invention as claimed. The specification teaches a process for reducing evaporation in a single aqueous solution i.e. a PCR reaction droplet (page 3, last paragraph and pages 23-56) and the specification teaches that the invention is "effective for a biochemical reactions other than PCR which involves a high temperature reaction" (page 8, bottom paragraph). While the specification teaches the actual reduction to practice of a droplet containing a PCR reaction and while the specification suggests the process is effective for other non-specific biological reaction droplets, the specification does not teach reduction to practice of the very large genus of claimed aqueous solutions. Therefore, the specification does not teach an actual reduction to practice of the invention as claimed.

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Completed by drawings

The claims are drawn to a process for reducing evaporation in a minute droplet of an aqueous solution. The specification illustrates by drawing a process for reducing evaporation in a droplet comprising a PCR solution. However, the specification does not teach that the invention as claimed is complete as evidenced by drawings because the drawings do not teach or illustrate reducing evaporation of the very large genus of claimed aqueous solutions. Drawings which provide evidence of the claimed process for reducing evaporation would encompass graphs, charts and/or data illustrating reducing evaporation as claimed. The drawings of the specification illustrate droplets on a substrate immiscible with an oily layer (Fig. 1-42). But the drawings do not provide evidence that the invention is complete because the drawings do not illustrate or complete the description of the claimed reducing evaporation. Therefore, the drawings do not teach or complete a teaching of the claimed process.

Description of identifying characteristics

The claims are drawn to a process for reducing evaporation in a minute droplet of an aqueous solution. The claimed process encompasses a very large genus of aqueous solutions, biological and non-biological, each comprising a myriad of components each comprising a very large genus of component concentrations and each comprising a very large genus of solution characteristics e.g. pH, thermal properties, and viscosities. Each of the claimed species requires specific preparations and conditions to obtain the claimed results i.e. reducing evaporation. The specification teaches a process for reducing evaporation in a PCR reaction (page 3, last paragraph and pages 23-56) and the specification suggests that the invention is "effective for a biochemical reaction other than PCR which involves a high temperature reaction" (page 8, bottom paragraph). The specification does not teach identifying

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characteristics of the claimed solutions e.g. solution compositions, solution characteristics and /or solution preparations which define the claimed process. Therefore, the specification has not been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention.

The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention see *In re Vas-Cath, Inc.* 935F2d. 1555, 1563, 19 USPQ2d 1111,1116.

The specification does not provide a written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Therefore, the specification does not provide an adequate written description of the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21, 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. al. (U.S. Patent No. 5,589,604, issued 31 December 1996) in view of Wakayama et al (U.S. Patent No. 6,331,659, filed 21 January 1998).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Regarding Claim 21, Drohan et al. teach a method for reducing evaporation in minute droplet of an aqueous solution comprising micromanipulation of embryos under a oily layer (Column 9, lines 34-36) comprising the steps of providing a planar substrate (petri dish); providing an oily liquid layer (silicone oil covering the microdroplet); providing an aqueous solution immiscible with said oil layer (DNA solution); shooting a minute droplet of said aqueous solution into said oily layer (microinjecting the DNA into the embryo); wherein said oily layer surrounds all surfaces of said minute droplet of aqueous solution that are not in contact with said planar substrate whereby evaporation is reduced (Column 9, lines 32-45) but they do not teach the microinjection is via ink jet technique. However, Wakayama et al teach the similar embryo micromanipulation wherein the microinjection is via an ink jet technique. Specifically, Wakayama et al teach the method comprising the steps of providing a planar substrate (petri dish); providing an oily liquid layer (mineral oil covering the microdroplet); providing an aqueous solution immiscible with said oil layer (DNA solution); shooting a minute droplet of said aqueous solution into said oily layer (Column 15, lines 20-44) wherein the micro injection is via ink jet technique (piezo micromanipulator)(Column 10, lines 33-67) wherein their piezo micromanipulator provides rapid and efficient delivery thereby reducing trauma to the cells (Column 8, lines 12-15). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ink jet technique of Wakayama et al to the microinjection of Drohan et al to thereby rapidly and efficiently manipulate the embryos with reduced trauma for the expected benefit of obtaining highly successful microinjection as taught by Wakayama et al (Column 8, lines 12-24).

Regarding Claim 25, Drohan et al teach the process wherein the oily layer comprises silicone oil (Column 9, lines 34-36) and Wakayama et al teach the similar process wherein the oily layer comprises mineral oil (Column 15, lines 31-34).

Regarding Claim 32, Drohan et al does not teach providing a second aqueous droplet. However, Wakayama et al teach the similar method comprising providing a second aqueous

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solution into said oily liquid layer adjacent to said minute droplet wherein said second solution does not contact said minute droplet i.e. during the enucleation step, the removed chromosomes are discharged into the surrounding environment thereby providing a second aqueous droplet adjacent to the minute droplet (Column 9, lines 40-44). Wakayama et al teach this method step is preparatory for enucleation of adjacent oocytes (Column 9, lines 40-44) which suggests that the method step increases efficiency of the method. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the second droplet of Wakayama et al to the enucleation of Drohan et al to thereby enucleate multiple oocytes for the expected benefit of efficiency and economy of time as suggested by Wakayama et al (Column 9, lines 40-44).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. al. (U.S. Patent No. 5,589,604, issued 31 December 1996) in view of Wakayama et al (U.S. Patent No. 6,331,659, filed 21 January 1998) as applied to Claim 21 above and further in view of Falcon Plastics (www.bdbiosciences.com/discovery_labware/Products/cell_cultureware/bacteriological_petri_dishes) and Parker, S. ed. (McGraw-Hill Dictionary of Chemical Terms, McGraw-Hill Book Co., NY, 1985, page 341)

Regarding Claim 22, Drohan et al. teach a method for reducing evaporation in minute droplet of an aqueous solution comprising micromanipulation of embryos under a oily layer (Column 9, lines 34-36) comprising the steps of providing a planar substrate (petri dish); providing an oily liquid layer (silicone oil covering the microdroplet); providing an aqueous solution immiscible with said oil layer (DNA solution); shooting a minute droplet of said aqueous solution into said oily layer (microinjecting the DNA into the embryo); wherein said oily layer surrounds all surfaces of said minute droplet of aqueous solution that are not in

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contact with said planar substrate whereby evaporation is reduced (Column 9, lines 32-45) but and Wakayama et al teach the similar embryo micromanipulation wherein the microinjection is via an ink jet technique. Drohan et al teach the process wherein the substrate is a petri dish (Column 9, lines 32-34) but they are silent regarding composition or water repellency of the petri dish. Wakayama et al teach the similar method wherein the substrate is a plastic dish i.e. Falcon cat. No. 1001 (Column 15, lines 20-24). Falcon teaches their plastic dish # 1001 is comprised of polystyrene (Falcon Plastics, web site) which is a water repellent material (i.e. a hydrocarbon) as taught by (McGraw-Hill Dictionary of Chemical Terms, page 341). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the water repellent dish of Wakayama et al in the method of Drohan et al and to provide a water repellent substrate. One skilled in the art would have been motivated to provide a water repellent substrate because the droplet of aqueous solution would bead (i.e. not spread) on the water repellent substrate and thereby retain its position on the substrate and its droplet shape. One skilled in the art would have been motivated to retain the position and shape of the droplet for the expected benefit of manipulating and observing reactions within the retained droplet.

7. Claims 29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. al. (U.S. Patent No. 5,589,604, issued 31 December 1996) in view of Wakayama et al (U.S. Patent No. 6,331,659, filed 21 January 1998) as applied to Claim 21 above and further in view of Monk et al. (Mammalian development: a practical approach, 1987).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Regarding Claims 29 and 33, Drohan et al. teach a method for reducing evaporation in minute droplet of an aqueous solution comprising micromanipulation of embryos under a oily layer (Column 9, lines 34-36) comprising the steps of providing a planar substrate (petri dish); providing an oily liquid layer (silicone oil covering the microdroplet); providing an aqueous solution immiscible with said oil layer (DNA solution); shooting a minute droplet of said aqueous solution into said oily layer (microinjecting the DNA into the embryo); wherein said oily layer surrounds all surfaces of said minute droplet of aqueous solution that are not in contact with said planar substrate whereby evaporation is reduced (Column 9, lines 32-45) but and Wakayama et al teach the similar embryo micromanipulation wherein the microinjection is via an ink jet technique (Column 10, lines 32-67). Drohan and Wakayama et al do not teach a covering over said oily layer. However, Monk et al teach a similar process comprising the steps of providing a planar substrate; providing an oily liquid layer; providing an aqueous solution immiscible with said oil layer (DNA solution); and shooting a minute droplet of said aqueous solution into said oily layer wherein said oily layer surrounds all surfaces of said minute droplet of aqueous solution that are not in contact with said planar substrate and wherein a covering is provided over said oily liquid layer i.e. the bottom of the chamber comprises the covering over the liquid paraffin layer for observing the manipulation under a microscope (page 245, Fig 4b). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the covering of Monk et al to the micromanipulation of Drohan et al and Wakayama et al based on available observation apparatus (e.g. microscope) for the obvious benefits of observing micromanipulation using available equipment.

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NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given A PERIOD OF TIME WHICH IS CO-EXTENSIVE WITH THE TIME TO REPLY WITH THE ABOVE OFFICE ACTION within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

9. Claims 34 and 37-39 are free of the prior art of record and may be placed in condition for allowance following resolution of the above rejections.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

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application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 23, 2002